Issue Snapshot:
Modified Risk Tobacco Products (MRTPs)

The 2009 Family Smoking Prevention and Tobacco Control Act ushered in a new era of tobacco control—giving the U.S. Food and Drug Administration (FDA) a powerful tool to create a healthier future for America's families by regulating the manufacture, distribution, and marketing of tobacco products. One of the ways FDA is working to improve public health is by ensuring that tobacco products marketed with claims of reduced harm or risk of tobacco-related disease actually *do* reduce harm or risk of disease. In addition, such "modified risk tobacco products" (MRTPs) must also benefit the health of the population as a whole. FDA rigorously serves as a regulatory gatekeeper, protecting consumers from modified risk claims that are not backed by science. As of June 2015, FDA has not yet authorized any tobacco products to be marketed as MRTPs, although several applications are under review.

What is a Modified Risk Tobacco Product (MRTP)?

An MRTP is a tobacco product that may be sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Aspects of MRTP marketing may communicate to consumers that the product:

1. is less harmful or presents a lower risk of tobacco-related disease than other commercially marketed tobacco products,
2. reduces exposure to a harmful substance, or
3. does not contain or is free of a harmful substance.

A product labeled or advertised and used to treat tobacco dependence, or to help people quit tobacco use, is not an MRTP and must be approved as a drug or device by FDA.

A History of Concern

In the past, tobacco companies marketed some cigarettes as "light," "low," or "mild." This marketing encouraged current smokers to perceive light, low, or mild cigarettes as safer alternatives and switch to these products rather than quit altogether. The marketing also encouraged greater experimentation and initiation among non-users. Consumers mistakenly believed that light, low, or mild cigarettes caused fewer health problems than other cigarettes. However, studies showed that there was no reduction in health risk from such products, and that they may actually have increased the dangers of tobacco use.

As a result, Congress set high standards to ensure that the marketing of tobacco products does not again mislead the public about the relative risks of such products. Congress directed FDA to review MRTP applications to ensure that marketing and claims about the risks of tobacco products are substantiated and supported by scientific evidence, and that advertising and labeling help the public better understand these claims in relation to overall health. FDA must consider the potential impacts, such as the likelihood that users who would have otherwise quit tobacco use will instead switch to the MRTPs or use MRTPs along with other tobacco products, or the likelihood that non-users of tobacco products will start using an MRTP.

Unique MRTP Review Requirements

In addition to rigorous scientific review, MRTP applications have additional, unique requirements. For example, FDA must make MRTP applications available to the public for comment (while removing commercial and confidential information from public

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view). Also, FDA must refer MRTP applications to the Tobacco Products Scientific Advisory Committee (TPSAC), which provides advice to FDA. While advice from TPSAC is not binding, FDA considers it along with other relevant information (including public comments) when making a final decision.

MRTP Orders and Postmarket Monitoring and Studies

By law, tobacco products may not be marketed with claims that they reduce harm or the risk of tobacco-related disease without a written order from FDA. There are no authorized MRTPs on the market in the United States, although several applications are under review. After an MRTP order is granted, applicants must conduct postmarket studies on their products and must monitor or track product use. FDA will monitor MRTPs and review annual reports from applicants that receive a MRTP order. In addition, FDA grants an MRTP order for a fixed period of time that is specified in the order letter. Furthermore, FDA must withdraw an MRTP order if a product no longer meets the conditions of the FD&C Act.

Further Information

For more information, including draft guidance documents, a summary of MRTP applications and FDA decisions (as applicable), as well as links to publicly available versions of MRTP applications, visit FDA.gov and search on “modified risk tobacco product.”

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